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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,402	12/22/2003	Randolph Stanley Porubcan	PRB-1	7174
7590	06/01/2005		EXAMINER	
Bioarray Solutions 35 Technology Drive Warren, NJ 07059				TONGUE, LAKIA J
		ART UNIT	PAPER NUMBER	
			1645	

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/743,402	PORUBCAN, RANDOLPH STANLEY	
	Examiner Lakia J. Tongue	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 December 2004.
- 2a) This action is FINAL.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-6,8-13,28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 14-27 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-6,8-13 and 29 is/are rejected.
- 7) Claim(s) 28 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

**DETAILED ACTION**

Applicant's response filed on March 3, 2005 is acknowledged. Claims 1-6, 8-13 and newly added claims 28-29 are pending and under consideration. Claims 7 and 14-27 have been canceled.

The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

***Rejections Withdrawn***

1. In response to applicant's amendment, the rejection of claims 1-13 under 35 U.S.C. 112, page 4 is withdrawn.

***Rejections Maintained***

2. The rejection of claims 1-6, 8-13 and newly added claim 29 under 35 U.S.C. 102(e) is maintained for the reasons set forth in the previous Office Action page 5.

The rejection was on the ground that McGrath et al disclose an invention for storage and delivery of microorganisms. McGrath et al discloses a probiotic organism that refers to a live microbial feed supplement which beneficially affects the host animal by improving the intestinal microbial balance. Examples of probiotic microorganisms are Bifidobacterium, Lactococcus, Lactobacillus and Enterococcus (0018). McGrath et al disclose that the matrix comprises an alginate (0023). The formulation is provided in a form which is substantially free of water. The formulation may be freeze-dried, lyophilized or spray dried, or other wise dried by methods known in the art (0026). McGrath et al disclose a preferred embodiment as being probiotic cells grown in an

appropriate culture medium as known in the arts. The cells are preferably harvested by centrifugation and washed. The cells are then suspended in a solution of a soluble alginate salt. Preferred alginate salts include lithium, sodium, potassium, rubidium, etc., however, sodium alginate is used (0047). McGrath et al also disclose beads comprising immobilized or encapsulated microorganism may be formed by adding the medium (containing cells and alginate) into a calcium or other solutions (0049). McGrath et al further disclose the cells of the probiotic microorganisms may also be encapsulated in microspheres or microcapsules. Microcapsules containing the microorganisms may also be formed by internal gelation of an alginate solution emulsified with oil (0050). Table 1 on page 8 provides the stability of *E. faecium* EF-101 in the probiotic alginate formulations. The table depicts the size of the strain before encapsulation, 1 week, 1 month and 3 months after encapsulation. Lastly, McGrath et al disclose that the formulation may be kept or stored for extended periods of time in a dry, semi dry or moist state without compromising the viability of the microorganism (0027). Limitations such as administration, when to mix a probiotic or weight/volume ratios are being viewed as limitations of optimizing experimental parameters.

Applicant urges that a) McGrath et al does not disclose that the formulation has "a water activity of between 0.01-0.07, and wherein, upon exposure to an acidic environment, an alginic acid gel is formed which shields the probiotic bacteria from the antibiotic effects of the acidic environment", b) McGrath et al probiotic bacteria in the feed is not intended to be acid-resistant (acid resistance is not mentioned), c) McGrath et al mixture includes alginate, preferably a calcium or a barium alginate, however applicant urges that when sodium alginate is mixed with a "calcium-containing solution," a gel -like insoluble material forms- but an alginic acid gel does not form on contact with an acidic environment. Moreover, calcium compounds such as calcium carbonate are not used as carriers since an excess of calcium forms an insoluble gel with sodium alginate (page 7, instant application) and d) there is no mention or suggestion anywhere of conferring resistance to the bacteria to stomach acid.

It is the examiner's position that the claims are drawn to a formulation and not to a method of preparing a formulation. McGrath et al teach a formulation of

probiotic bacteria such as Lactobacilli or Bifidobacteria encapsulated in a probiotic such as cell cellulose (0114-0116). The probiotic cells can be formulated with alginate salts (0047). The formulation of McGrath et al is the same as the claimed composition.

Since the claims are drawn to a formulation, characteristics such as "upon exposure to an acidic environment, an alginic acid gel is formed which shields the probiotic bacteria from the antibiotic effects of the acidic environment", the ratio of sodium alginate, drying the formulation are viewed as process limitations. Characteristics such as water activity would be inherent in the formulation of McGrath. Additionally McGrath et al teaches formulations of probiotic microorganisms within the range of  $10^7$  to  $10^8$  organisms.

There is nothing on record to show (via a side-by-side comparison) that the formulation of McGrath et al is not the same and would not inherently have the claimed water activity.

***New Grounds of Rejection***

***Specification***

3. The disclosure is objected to because of the following informalities: on page 10, line 23 the word "shin" should be "skin".

Appropriate correction is required.

***Claim Objections***

4. Claim 28 is objected to for being depended on a rejected based claim.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 8, 9, 11 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. The limitation of a derivative of cellulose has not been disclosed in the instant specification. To overcome this rejection applicant must specifically point out the support for this limitation or cancel the new matter from the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 9,11 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what applicant intends by derivative. Applicant does not contemplate derivative in the instant specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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